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NDMA

NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION
Formerly The Proprietary Association

Better Health
Through Responsible
Self-Medication

February 14, 1992

VIA FAX

David A. Kessler, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Docket No. 78N-0065

Dear Commissioner Kessler:

This letter is in response to Mark Green's letter to you dated February 11, 1992 in which Mr. Green requests that all hydroquinone-containing topical skin "lightening" products marketed in the United States be seized and banned. Mr. Green's request arises from his allegations of misbranding based upon putative deviations from preamble statements and proposed labeling specifications set forth in the 1982 proposed monograph for Skin Bleaching Drug Products (47 FR 39108, September 3, 1982) and an uncritical review of: (a) in Mr. Green's words, anecdotal reports of exogenous ochronosis, primarily in South Africa where conditions of use have been dramatically different than in the United States and where significantly different formulations are used; and (b) a recently published National Toxicology Program (NTP) report of oral bioassay studies in rodents fed via gastric lavage at doses substantially greater than that available through dermal application of OTC preparations from which hydroquinone (HQ) is poorly absorbed.

The Nonprescription Drug Manufacturers Association (NDMA) Hydroquinone Task Group is confident that a thorough critical review of the facts and existing database will convince the agency that the industry, as represented on the Task Group, has acted and is continuing to act responsibly in addressing all issues pertaining to the safe and effective use of HQ on the OTC marketplace and that the 1982 proposed Category I status for HQ (i.e., generally recognized as safe and effective) continues to be an appropriate classification. We request that sufficient time -- of an appropriate period to respond to the scientifically unfounded allegations raised by Mr. Green (e.g., 90 days) -- be granted to the Task Group to enable us to prepare our detailed data in an appropriate format for submission to FDA before FDA takes any further action in this area. This would require opening of the administrative record,

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which we request at this time. As you may know, the NDMA Task Group has already requested a meeting with FDA to discuss the NTP study (see enclosed letter to Dr. Botstein), and we hope that this meeting can also be accomplished before any further action is taken in this area by FDA.

More specifically, a critical review of the facts will reveal that upon publication of the proposed monograph the HQ products addressed by the Task Group were modified where deemed appropriate so as to reflect the primary findings of the proposed rulemaking. This action was undertaken by members of the Task Group:

(a) Despite the fact -- as evidenced by their and their predecessors' comments to the proposed rulemaking docket -- that they disagree with the appropriateness of several of the preamble statements and the proposed findings and specifications of the proposed monograph;

(b) Despite the very relevant fact that the proposal of a rulemaking clearly does not constitute a binding rule or obligation; .

(c) Despite the fact that -- subsequent to the publication of the 1982 proposed rule which envisioned a requirement for use only of the specified indication language (i.e., applying the so-called "exclusivity rule") -- FDA abandoned its exclusivity policies and specifically authorized the use of alternative language, so long as that language is consistent with the described indications and is neither false nor misleading.

A critical review of the facts and database will also reveal that, while 2% HQ was proposed for Category I status in 1982 and while the administrative record pertaining to this rule is currently closed, the Task Group monitored the docket as well as the relevant published scientific literature pertaining to HQ. Where old issues have resurfaced (e.g., ochronosis)[1] or new issues arise (e.g., the NTP Study, see enclosed letter to Dr. Botstein dated February 11, 1992), the Task Group has, with consultation of leading experts in the appropriate scientific and medical disciplines, undertaken to address these issues scientifically. As stated

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[1] The possibility of ochronosis occurring was specifically addressed in both the 1978 Advanced Notice of Proposed Rulemaking and the 1982 Proposed Rule. (See, 43 FR 51549, November 3, 1978 and 47 FR 39110, September 3, 1982)

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above, the Task Group requests the opportunity to place this information into the administrative record at this time before FDA undertakes any further action.

In summary, as stated above, our assessment of the available data, much of which is not yet in the administrative record, leads us and outside experts with whom we have consulted to the conclusion that 2% hydroquinone continues to be recognized as a safe and effective OTC preparation for treating variations in skin color which -- in the words of FDA's OTC Advisory Panel -- "may not only constitute a cosmetic liability, but in many instances produces formidable emotional and social problems" (43 FR 51551, November 3, 1978).

We look forward to your early response on this matter.

Sincerely yours,

R. William Soller, Ph.D.

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

Enclosure: Letter From Dr. Soller to Dr. Botstein Dated February 11, 1992.

WS/kfm